FEB 2 2 2012 K 113570

510(k) Summary

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

807.92(a)(1) - Submitter Information	
Name	Integra Burlington MA, Inc.
Address	22 Terry Avenue Burlington, MA 01803
Phone number	609-936-5583
Fax number	609-275-9447
Establishment Registration Number	1222895
Name of contact person	Lindsay Mignone
Date prepared	November 30, 2011
807.92(a)(2) - Name of device	
Trade or proprietary name	Integra™ CUSA NXT™ Inferior Forward Bone Tip
Common or usual name	Ultrasonic Surgical Aspirator
Classification name	Instrument, Ultrasonic Surgical
Classification panel	General and Plastic Surgery
Regulation	Unclassified
Product Code(s)	LFL
807.92(a)(3) - Legally marketed device(s) to which equivalence is claimed	
	CUSA NXT Bone Tips (K111741)
807.92(a)(4) - Device description	
	The Integra CUSA NXT Inferior Forward Bone Tip (Inferior Forward Bone Tip) will attach to the Selector 24 kHz Neuro Short Handpiece (1523000M7) and will be controlled by the CUSA NXT Ultrasonic Surgical Aspirator System (CUSA NXT System). The CUSA NXT System is an ultrasonically vibrating surgical device which, in combination with irrigation and aspiration, fragments, emulsifies and removes unwanted tissue. The device allows the selective dissection of target tissue while preserving vessels, ducts and other delicate structures. The system consists of a console which provides control and power functions, a surgical handpiece which provides ultrasonic mechanical energy, a single use tip, and a suction/irrigation system (manifold tubing and cooling water canister). The Inferior Forward Bone Tip has an abrasive surface that is oriented inferiorly and distally at the distal end of the tip. This configuration facilitates the use of the system in procedures where it is necessary for practitioners to orient the surgical tip in the bottom dead center or inferior orientation.

	The Inferior Forward Bone Tip consists of a titanium tip with a titanium nitride coating, silicone flue and an ultem shroud. The Inferior Forward Bone Tip will be supplied sterile and is intended for single use.
807.92(a)(5) Intended use of the device	
Indications for use	The CUSA NXT Inferior Forward Bone Tip is an accessory to the CUSA NXT Ultrasonic Surgical Aspirator System that is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft and hard (e.g. bone) tissue is desirable, including Neurosurgery, Gastrointestinal and affiliated organ surgery, Urological surgery, Plastic and Reconstructive surgery, General surgery, Orthopedic surgery, Gynecological surgery, Thoracic surgery, Laparoscopic surgery and Thoracoscopic surgery. The indications for use for the CUSA NXT system have not changed due to the addition of the Inferior Forward Bone Tip.

807.92(a)(6) Summary of the technological characteristics of the device compared to the predicate

Characteristic	CUSA NXT Inferior Forward Tip	CUSA NXT Bone Tips (K111741)
Console used with tip	CUSA NXT Ultrasonic Surgical Aspirator System	CUSA NXT Ultrasonic Surgical Aspirator System
Approximate Frequency of Operation	24 kHz	24 kHz
Max Stroke (inches)	0.0120	0.0120
Tips Delivered As	Sterile / Single Use	Sterile / Single Use
Shroud	Uses a curved shroud, packaged with tip	Uses a curved shroud, packaged with tip
Vibration of Tip	Longitudinal	Longitudinal
Design of distal end	Protrusion with 10° inverse conical	Protrusion with 10° inverse conical (Forward) Protrusion with 10° conical (Reverse)
	Abrasive surface oriented inferior to surgical tip when bent	Abrasive surface oriented superior to surgical tip when bent
Pre-aspiration holes	Yes	Yes
Inner Diameter (inches)	0.078	0.078
Working Length (mm)	88	88 (Forward) 80 (Reverse)
Bend Angle	20°	20°
Bend Radius (in)	5.684	3.15
Material		
Tip	Titanium 6AL4V Grade 5	Titanium 6AL4V Grade 5
Flue	Silicone	Silicone
Shroud	Ultem	Ultem

807.92(b)(1-2) Nonclinical tests submitted	
Test	Result
Electromechanical Test – measures frequency, stroke, lateral movement, and power	Passed frequency, stroke, lateral movement, and quiescent power acceptance criteria.
Lateral Load Test – applies a lateral load on the vibrating tip to evaluate robustness	Performance of the tips was not affected after the application of the lateral load.
Dry Flue Test – checks the effect of ultrasonically vibrating a surgical tip without the presence of irrigation	Performance of the tips was not affected when operated with no irrigation for the time specified.
Accelerated Stress Bone Cutting – tests the effect of bone cutting for extended periods of time	No breakage of the abrasive surface occurred.
Measurement of Thermal Rise During Ultrasonic Aspiration of Representative Tissue	Thermal rise in tissue field during tissue removal was found to be less than stated in the product specification.
Biocompatibility	Since the modified device uses materials that have the same chemical formulations, same manufacturing and same sterilization processes as in the predicate device, additional testing was not performed.
807.92(b)(3) Conclusions drawn from non-clinical data	
Testing confirmed that the performance of the Inferior Forward Bone Tip meets the product specification, which is based on the predicate CUSA NXT Bone Tips. Therefore, the modification resulted in a device that performs the same as the predicate device.	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Integra Burlington MA, Incorporated
% Ms. Lindsay Mignone
22 Terry Avenue
Burlington, Massachusetts 01803

FEB 2 2 2012

Re: K113570
Trade/Device Name: Integra CUSA NXT Inferior Forward Bone Tip
Regulatory Class: Unclassified
Product Code: LFL
Dated: November 30, 2011
Received: December 2, 2011

Dear Ms. Mignone:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

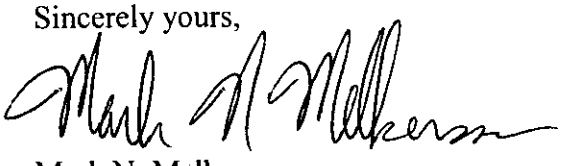
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K113570

Device Name: Integra CUSA NXT Inferior Forward Bone Tip

Indications for Use:

The Integra CUSA NXT Inferior Forward Bone Tip is an accessory to the CUSA NXT Ultrasonic Surgical Aspirator System that is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft and hard (e.g. bone) tissue is desirable, including Neurosurgery, Gastrointestinal and affiliated organ surgery, Urological surgery, Plastic and Reconstructive surgery, General surgery, Orthopedic surgery, Gynecological surgery, Thoracic surgery, Laparoscopic surgery and Thoracoscopic surgery.

PRESCRIPTION USE __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113570